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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WELLS, LAUREN Q

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/425,742

Applicant(s)

KRAEMER ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10-23,28 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 1-23, 28-29 are pending. Claims 3 and 9 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 11/1/02, cancelled claims 24-27 and amended claims 1, 22-23, and 28-29.

As Applicant has provided no arguments, there is no "Response to Arguments" in this action.

#### ***Request for Continued Prosecution Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/1/02 has been entered.

#### ***Election/Restrictions***

A call to Carol Einaude on 11/22/02, confirmed that the election of species requirement and election, made of record in Paper No. 7, is maintained.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(i) Claim 10 is vague and indefinite, as it is confusing. See lines 4 and 5—are not “acrylate copolymers” and “acrylic acid ester copolymers” synonymous? Furthermore, is Applicant claiming a range within a range? Claim 10 recites multiple acrylic acid ester/acrylate copolymers, such as ethylene/acrylic acid ester copolymer (line 11), acrylic acid/acrylic acid ester copolymers (third to last line).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois (5,558,859) in view of Dubois (6,162,444).

The instant invention is directed toward a composition comprising a film-forming agent, a physiologically tolerated solvent, a plasticizer, and a generic phenylimidzolidone compounds, processes for making the composition, and processes for using the composition.

Cretois teaches compositions for the treatment and protection of the exoskeletal parts, such as hair and skin, comprising in a cosmetically acceptable medium, at least one ceramide and/or glycoceramide and at least one vinylpyrrolidone polymer. Polyoxyethylenated carboxylic ether acids are disclosed as anionic surfactants that are added to the composition. Water and alcohols, such as ethanol and isopropanol, and combinations thereof are disclosed as cosmetically acceptable mediums. Antiseborrhoeic agents are disclosed as additives. Exemplified is a hair care composition comprising Luviquat FC 905 (plasticizer, copolymer of

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vinylimidazolium methochloride and vinyl pyrrolidone) and Cremophor RH 410 (film forming agent, polyethoxylated hydrogenated castor oil). The reference lacks instant formula (I) and 5-alpha-reductase inhibitors. See Col. 1, line 6-Col. 2, line 11; Col. 4, line 43-Col. 12, line 16.

Dubois teaches topical cosmetic or pharmaceutical compositions containing a dermatologically effective amount of at least one liposome containing a compound of formula (I), wherein the compound of formula (I) is synonymous to the compound of formula (I) of the instant claims. Gel, cream, milk, balm, and lotion forms of the composition are disclosed. The liposomes are disclosed as being comprised of sphingolipids (ceramides). 5-alpha reductase inhibitors such as 1,1-dimethylethyl-3-oxo-4-aza-androstene-17 carboxamide and Minoxidil (6-amino-4-piperidino-1,2-dihydro-1-hydroxy-2-iminopyrimidine) are disclosed as additives. The composition is disclosed for treating seborrhea. See Col. 1, line 24-Col. 7, line 9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the liposome containing formula (I) of Dubois into the composition of Cretois because a) Dubois and Cretois are both directed to topical cosmetic compositions; b) Cretois teaches the addition of antiseborrhoic agents to his composition and the compound of formula (I) is an antiseborrhoic agent that is encapsulated in a liposome such that the concentration of the active agent in the sebaceous is higher and longer-lasting in the epidermis and dermis, minimizing the passage of the active agent into the blood circulation; c) Cretois teaches ceramides as an essential ingredient of his compositions and the liposomes of Dubois are comprised of ceramides; thus, one of skill in the art would be motivated to add the liposomes containing formula (I) of Dubois into the composition of Cretois because of the expectation of

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achieving an anti-seborrhoic composition that is more effective and longer lasting, and which does not result in adverse side-effects as a result of seeping into the circulatory system.

Note: Regarding the limitation “wherein said compound of formula I is released from the film formed by application of said composition to a skin surface”, the Examiner respectfully points out that this limitation is a property of the composition and its constituents. Thus, the same composition with the same constituents will have the same property.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois and Dubois as applied to claims 1-2, 4-8, 10-13, 16-17 above, and further in view of Lai (5,916,910).

Cretois and Dubois are applied as discussed above. The reference lacks angiotensin converting enzyme inhibitors.

Lai teaches conjugates of dithiocarbamates with pharmacologically active agents, wherein dithiocarbamates are disclosed as reducing cutaneous irritation and alopecia. Captopril, fosinopril, felopdipine, nicardipine, and nifedipine are disclosed as pharmacologically active agents. See Col. 3, lines 49-51; Col. 8, lines 51-54.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the captopril of Lai to the composition of the combined references because the combined references and Lai are both directed toward compositions comprising minoxidil that treat alopecia, and Lai teaches captopril and minoxidil as combinable; thus, one of skill in the art would be motivated to add captopril to the composition of the combined references because of the expectation treating alopecia and hypertension.

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Claim 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois in view of Dubois as applied to claims 1-2, 4-8, 10-13, 16-17 above, and further in view of Ismail (5,541,220).

Cretois and Dubois are applied as discussed above. The reference lacks methylxanthine compounds.

Ismail teach agents for the treatment and protection of the skin. Exemplified is a capsule that can treat alopecia comprising pentoxifyllin, vitamin E, and other ingredients. See Col. 8, example 24.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add pentoxifyllin to the composition of the combined references because Ismail and the combined references are directed to treating alopecia and Ismail teach pentoxifylline as increasing blood circulation; thus, one of skill in the art would be motivated to add pentoxifylline to the composition of the combined references because of the expectation of circulating the active agents of the composition through the body.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois in view of Dubois as applied to claims 1-2, 4-8, 10-13, 16-17 above, and further in view of WO 92/21317.

Cretois and Dubois are applied as discussed above. The reference lacks 2,4-diamino-6-butoxy-3-sulfonylpyrimidine hydroxide.

WO '317 teaches compositions containing a pyridine-1-oxide of formula (I) for combating hair loss and inducing/stimulating hair growth. Specifically disclosed is 2,4-diamino-6-butoxy-3-sulfonylpyrimidine hydroxide. See abstract.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the 2,4-diamino-6-butoxy-3-sulfopyrimidine hydroxide to the composition of the combined references because WO '317 and are all directed toward combating hair loss; thus, one of skill in the art would be motivated to add 2,4-diamino-6-butoxy-3-sulfopyrimidine hydroxide to the composition of the combined references because of the expectation of further combating hair loss.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cretois in view of Dubois as applied to claims 1-2, 4-8, 10-13, 16-17 above, and further in view of WO 91/19701.

Cretois and Dubois are applied as discussed above. The reference lacks preferred pyridine-1-oxides and 2,6-diamino-1,3,5-triazine compounds.

WO '701 teaches triazines of formula (I) for the prevention and treatment of hair loss. Specifically disclosed are 2,6-dimaino-4-piperidinopyridine and 2,6-diamino-4-butoxy-1,3,5-triazine 1-oxide. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the 2,6-dimaino-4-piperidinopyridine to the composition of the combined references because WO '701 and are all directed toward combating hair loss; thus, one of skill in the art would be motivated to add 2,6-dimaino-4-piperidinopyridine to the composition of the combined references because of the expectation of further combating hair loss.

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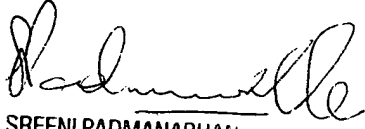
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
November 26, 2002

  
SREENI PADMANABHAN  
PRIMARY EXAMINER  
